IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Confirmation No.: 8538
Gallus Schechner, et al.	Group Art Unit: 1794
Serial No.: 10/528,842	Examiner: Nikki H. Dees
Filed: July 26, 2005	
For: COATED CHEWING GUM	

VIA EFS-WEB
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Sir:

1. I, Dr. Jörg Kowalczyk, a German citizen, residing at Franz-Schubert-Strasse 24, 67304 Eisenberg Steinborn, Germany, do hereby declare as follows:
2. I am a co-inventor of the above-identified U.S. patent application and I make this declaration in support of the patentability of the claims of the application. I am employed by Südzucker Aktiengesellschaft Mannheim/Ochsenfurt, which is the owner by assignment of this application. I have read and am familiar with the Office Action concerning this application issued by the United States Patent and Trademark Office on February 17, 2010, and in particular with the references cited by the Examiner, i.e., Kropf et al. DE 10063945 A1 (hereinafter "Kropf") and Greenberg et al. USP 5,980,955 (hereinafter "Greenberg") to reject the claims of our application.
3. I graduated from Technical University of Braunschweig with an Undergraduate degree in chemistry in 1988. Thereafter, I received a PhD degree in chemistry from Technical University of Braunschweig in 1990 .
4. Regarding my employment experience, I started working for Südzucker AG Mannheim/Ochsenfurt in 1992 as a group leader in the research and development

center, focusing among other things on the production of sugar free sweetener solutions using hydrogenation technologies. Between 1998 and 2008 I worked as the Head of Product Development in the Südzucker AG research and development center, focusing on Food, Pharmaceutical Excipient and Non Food Product development and Application Technology. Since 2008, I am a Senior Manager in the Südzucker Group Research Organisation.

5. I understand from reviewing the February 17, 2010 Patent Office Action that the Examiner is rejecting the claims of our application (nos. 1, 3-5, 7-32, 34, 35 and 37-42) as being allegedly unpatentable over the disclosure of Kropf in view of Greenberg. The Office Action states (in ¶13) with regard to the rejection that, "As Kropf teaches the composite of a protein and nanoparticle calcium salt for the remineralization of tooth enamel, as well [as] of the use of chewing gums to expose remineralizing agents to teeth, one of ordinary skill would have found it obvious to include the remineralizing agents of Kropf in traditional chewing gum compositions, as taught by Greenberg, in order to result in a chewing gum product containing nanoparticle-sized calcium in a form that has significant residence time in the mouth in order to improve the dental hygiene of the user, or mineralize the enamel or dentine of the user in the presence of the calcium particles." I respectfully disagree with the Examiner's determination for the reasons which follow.

6. The claims of our application are directed to a coated chewing gum and to a method for producing the chewing gum, as well as to methods for improving dental hygiene in a subject, mineralizing the tooth enamel of a subject and mineralizing the dentine of a subject, wherein the coated gum recited in the claims is chewed by such subject. The process for coating the chewing gum is a very complicated and sophisticated process that is largely dependent upon empirical observations and experience of an artisan of at least ordinary skill in this art. This is mostly due to features such as unpredictable interactions between the substances used as the primary coating material, the level of solids in the coating syrup, the presence or absence of other substances in the coating syrup, the coating conditions and the coating apparatus. In sum, changing any of the

ingredients and/or the temperatures or other reaction conditions while still producing an acceptable coating is not a trivial matter, i.e., particularly in light of the fact that, as is well known to those having at least an ordinary level of skill in the relevant field, even a small change such as a different concentration of the same compound can lead to significant differences in the coating so produced.

7. The Greenberg reference discloses coated chewing gum products wherein the coating comprises, *inter alia*, a small quantity of a food-acceptable poorly water-soluble calcium salt for purposes of improving the smoothness of the finished coating and thus providing an improved appearance to the finished product (see col. 1, first and second paragraphs). According to col. 2, last paragraph of Greenberg, the calcium salts used in the coating have a solubility of about 5 g/l in water at 10°C.

8. At the temperatures conventionally used for coating chewing gums, as disclosed in Greenberg (see, e.g., Examples 2 and 3) the calcium salts are completely or, at a minimum, almost completely dissolved. Such dissolution is of particular importance during the coating process since the calcium salts serve as seed crystals during coating, i.e., during successive application of the coating layers and the subsequent drying of such coating layers by water evaporation (see, e.g., col. 8 lines 20-25 which disclose a syrup temperature of 85°C and the use of intermittent drying periods).

9. During the drying process the moisture content of the applied coating medium that sticks to the chewing gum core is successively reduced. Additionally, the components of such coating medium, in particular the calcium salts and xylitol, successively crystallize out – thereby forming the desired crystalline coating layer. Such a coating system requires re-crystallization and at least partial solubility of the coating material, i.e., calcium salts in the present case, within the coating medium. Only under the indicated circumstances may the calcium salts be applied to a chewing gum core in a completely or partially dissolved form, i.e., in order to permit them to crystallize out during the drying step(s), thus resulting in a smooth coating having an even distribution of coating material. It is evident from

Greenberg that the process described therein relies mainly on the solubility of the calcium salts used in forming the coating medium and their expected re-crystallization behavior in order to ensure precipitation at the correct time and in the proper quantity to promote proper crystallization of all (or substantially all) of the coating material contained in the coating medium.

10. In contrast to what is disclosed in Greenberg, the Kropf reference does not relate to a chewing gum coating process. Rather, the reference is instead directed to adhesive dental films wherein the films are prepared by adding different poorly soluble calcium salts into a solution of a water soluble or swellable polymeric carrier material and subsequently drying the resultant dispersion to obtain the resultant film. The calcium salt used in forming the film has a solubility of less than 1 g/l in water at 20°C which, when compared to the solubility of the calcium salt as taught in Greenberg (i.e., 5 g/l in water at 10°C) represents more than a five-fold difference in solubility. Furthermore, taking into account that the solubilities in Greenberg and Kropf are measured at different temperatures (see above) and, furthermore, that it is well known that solubility mostly increases dramatically as the temperature is raised, the difference in the solubilities between Kropf and Greenberg must be taken to be even larger than the factor of 5 mentioned above.

11. Because of their extremely low solubility, one such as myself having at least ordinary skill in this art would not regard the calcium salts disclosed in Kropf as being suitable for functioning as seed crystals in a chewing gum coating process. More particularly, I would have expected that the calcium salts disclosed in Kropf would not dissolve sufficiently in a coating medium and, therefore, would not be suitable for application in at least a partially dissolved form in a coating medium on a chewing gum core.

12. Accordingly, the Greenberg reference teaches that not every calcium salt may be used in the coating process described therein. In fact, the reference thus teaches that only the specific poorly water-soluble salts disclosed in the subject reference meet the requirements for forming an acceptable coating and are thus suitable for use in the coating process as described in the Greenberg reference. Therefore,

taking the above into account I and anyone else having at least an ordinary level of skill in this art, would have no reasonable expectation of success in considering whether the calcium salts taught for use in the Kropf reference which, as demonstrated above, are much less soluble than the salts disclosed in Greenberg, could be successfully used in a coating process according to Greenberg.

13. Both the composition of the presently claimed chewing gum coating layer and the claimed method of preparing the coating and applying it to the chewing gum center are entirely distinguishable over the preparation of a dental adhesive film according to Kropf. The dental film is essentially prepared by simply mixing a polymer component with the active component, i.e., the calcium salt, in an alcoholic solution and subsequently drying the mixture in order to obtain the film. In contrast to the film disclosed in Kropf, the coating layer of a chewing gum, i.e., as presently claimed, does not employ an alcoholic solution, nor does it employ calcium salt-containing water-soluble or swellable polymer components. Furthermore, it is not obtained via a single simple drying step. The preparation and application of the coating layer, as claimed in our application, in contrast to the disclosure contained in Kropf, involves a complex preparation process, according to which components able to form a crystal layer on a chewing gum core, under controlled agitation, are applied in a liquid form to the core and then dried. This cycle is then repeated several times as necessary.

14. Kropf employs extremely poorly soluble calcium salts in a relatively technically simple system that does not require controlled crystallization of any of the coating components, in particular carbohydrates. On the other hand, Greenberg does employ a system that requires controlled re-crystallization of carbohydrates from a coating syrup onto the core of a chewing gum in order to form a smooth coating layer. Taking these distinctions into account, therefore, one such as myself having at least an ordinary level of skill in the relevant art would not have considered the extremely poorly soluble calcium salts, i.e., of Kropf, to be applicable in the coating process of Greenberg, i.e., requiring re-crystallization.

15. Another factor distinguishing the presently claimed coating layer is the fact that the presently claimed coating layer contains not simply calcium salts. Instead, the

coating recited in the present claims is comprised of calcium salt/protein composites. An artisan of at least ordinary skill in this field typically would not have considered using such a protein component with a calcium salt in a chewing gum coating process due to the fact that such protein components are known to soak up water and, thus, are very likely to negatively affect the crystallization of a carbohydrate, while additionally causing problems due to a significantly reduced solubility and an agglomeration behavior. Such agglomeration would be expected to result in an undesirable sticking together of the coating components, and/or the adherence of the coating components to the coating drum or the nozzle of the coating device. The deficiencies noted above, therefore, have led to the establishment of a strong prejudice in this field of art against the use of a calcium/protein component in a process requiring the re-crystallization of carbohydrates, i.e., particularly in the coating of chewing gum cores.

16. As noted by the Examiner, the Kropf reference (see, e.g., paragraph [0003]) mentions lozenges and chewing gums as suitable carriers for introducing certain active components onto the tooth surface. This is due to the fact that such carriers have a relatively long residence time in the mouth. However, the Kropf reference entirely fails to mention that the calcium salts recited in present claim 1, or even that calcium salt/protein composites, would be suitable for use in chewing gums. That is, only dental adhesive films are identified as suitable carriers.

17. I submit that even if the reference to chewing gum preparations in Kropf were somehow linked to the specific calcium salts recited in the claims of the present application, or even to the use of calcium salt/protein composites (which, as noted in the paragraph above, they are not), such combination still would not teach, or even suggest, the composition and method as recited in the claims of our application. That is, the general disclosure in Kropf pointing to the use of chewing gums for providing effective agents to the surface of a subject's teeth does not teach or suggest to use coatings upon the surface of such chewing gum(s) to accomplish the desired end. As one familiar with the subject matter in this art, the coating of a chewing gum typically has an entirely different composition than that of the chewing gum core. That is, a chewing gum core consists mainly of a

chewing gum base having a flexible matrix-like structure. The enveloping coating, on the other hand, does not comprise a chewing gum base. In contrast, it is comprised of a formulation designed to be readily dissolvable in water for facilitating the release of sweetness, aroma and other ingredients. Thus, the requirements for a substance to be embedded in a chewing gum core are entirely different than for ingredients used in the coating. In light of these considerations, even if I, as one having at least ordinary skill in this field, had considered the general disclosure in Kropf relating to chewing gums in general as a motivating factor in suggesting the use of the calcium compositions also disclosed in Kropf in chewing gums, the suggestion would have involved including the calcium composites in the chewing gum core and not in the coating of the chewing gum.

18. In support of my conclusion at the end of the previous paragraph I respectfully cite the Examiner to paragraph [0011] of the Kropf reference which teaches that it is crucial that the active components be released from the support over a relatively long period and that the support material, i.e., an adhesive film, should not dissolve too rapidly in the mouth. As one skilled in this art, I know that the coating upon a chewing gum base does, in fact, dissolve rapidly, primarily due to the fact that the coating is mainly formed of sugars or sugar alcohols. The Kropf reference thus teaches away from including the active components, i.e., calcium salt or calcium salt/protein composites, in the coating of a chewing gum.

19. Along the same lines, Greenberg, at col. 4, lines 48-51, states that the water-soluble portion, i.e., the coating, of the gum, dissipates with a portion of the flavor over a period of time while the gum is chewed, after which only the gum base portion is retained in the subject's mouth. Taking this teaching, as well, into account, as one having at least an ordinary level of skill in this field of art, I would not have considered that including the calcium salt composites described in Kropf into the chewing gum coating (as described in Greenberg) would, firstly, produce an acceptable chewing gum coating and, secondly, would have produced a beneficial effect upon the teeth on a subject who chewed such gum.

20. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and

further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the application or any patent issuing thereon.

Date: 12th of May 2010 By: _____
Dr. Jörg Kowalczyk